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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,698	12/01/2003	Stephen D. Pacetti	50623.232	3424

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EXAMINER	
NGUYEN, PHU HOANG	
ART UNIT	PAPER NUMBER
1791	
MAIL DATE	DELIVERY MODE
12/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/725,698	PACETTI, STEPHEN D.	
	Examiner	Art Unit	
	PHU H. NGUYEN	1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/7/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-75* is/are pending in the application.

4a) Of the above claim(s) *6,8 and 57-75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,9 and 10* is/are rejected.

7)☒ Claim(s) *11-56* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :7/19/2004, 6/8/2005 and 11/7/2008.

DETAILED ACTION

Election/Restrictions

Acknowledgement is made of Applicant's election of the species received on 8/27/2008 as follows:

Species 1: Adjusting temperature during a crimping step;

Species 2: Tg of the polymer species is below ambient temperature;

Species 3: Target temperature is below ambient temperature;

Species 4: poly(vinylidene fluoride-co-hexafluoroproylene);

Species 5: Balloon expandable stents; and

Species 6: anitproliferatives.

Therefore, Claims 6 and 8 are drawn to non-elected species.

Applicant's election with traverse of group I, claims 1-56 in the reply filed on 8/27/2008 is acknowledged. The traversal is on the ground(s) that invention I has claim 3, which is dependent from claim 1, requires crimping of the medical device, such as a stent (claim 9), to a catheter which is the same as the step of invention II. This is not found persuasive because claim 9 of invention I recites the limitation of a stent grafts which is different from the stent of invention II which has no covering and therefore the crimping step of a stent has a materially different mode of operation than that of a stent graft (has special fabric supported by a stent).

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

It is noted that the IDS filed 7/19/2004 contains an extremely large number of references for consideration by the Examiner. If the applicant or applicant's representative's are aware of any particular reference or portion of a reference in the list which the examiner should take pay particular attention to it is requested that it be specifically pointed out in response to this Office action.

Claim Objections

Claims 11-56 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 11, should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims 11-56 have not been further treated on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Hijlkema et al. (U.S Pub. No. 20020143382).

Regarding claims 1-2, Hijlkema discloses a method of making a medical device comprising a coated piece wherein the coated piece comprises a coating, wherein the method comprises thermal regulation (corresponding to the claimed "adjusting temperature") of the coating to a target temperature during the

reconfiguration (corresponding to the claimed "crimping step" (closing the crimper and opening the crimper)) (Abstract and pargraph 47).

Regarding claim 3, Hijlkema discloses the device further comprises a catheter and wherein the crimping step attaches the coated piece to the catheter (paragraph 4).

Regarding claim 9, Hijilkema discloses the coated piece is a balloon expandable stents (paragraphs 4 and 42).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hijlkema et al. (U.S Pub. No. 20020143382) in view of Rosenthal et al. (U.S Pub. No. 2003/0144727). Although Hijlkema does not expressly disclose the coating comprises antiproliferative drug, it is well known in medical devices such as stents for delievering a biologically active material to a desired location within the body of a patient wherein the biologically active material includes agents such as antiproliferative as shown by Rosenthal (paragraphs 1 and 121-126). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the well known biologically active agent for the stent of Hijlkema.

Claims 4-5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hijlkema et al. (U.S Pub. No. 20020143382) in view of Pacetti (U.S Patent No. 6574497). Hijilkema discloses the coating comprises a polymer (paragraph 21) and a polymer can have a Tg below or above ambient temperature depending on the ambient temperature and the temperature of the existing surface of the coating may be either heated or cooled (paragraph 30). Although Hijikema does not expressly disclose the coating comprises poly(vinylidene fluoride-co-hexafluoroproylene), it is well known to use a fluorine containing elastomer such as copolymers of chlorotrifluorethylene and vinylidene fluoride to be affixed to a medical device as evidenced by Pacetti (column 9, lines 5-25).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 7 and 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 6 and 8 of copending Application No. 10957022. Although the conflicting claims are not identical, they are not patentably distinct from each other because these claims recite a method of making a medical device (these medical devices vary between the two applications) with identical method steps.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Applicant is advised that should claim 1 be found allowable, claim 2 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PHU H. NGUYEN whose telephone number is (571)272-5931. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Phillip Tucker can be reached on 571-272-1095. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

P.N 12/5/2008

/Philip C Tucker/
Supervisory Patent Examiner, Art Unit 1791